

Appl. 10/066,831  
 Amtd. Dated 10/10/04  
 Reply to Final Office Action of 04/27/2004

Table1. Cont

CLAIMS FROM USSN 10/066,831	CLAIMS FROM US 6,394,209	CLAIMS FROM US 6,419,801
		20. A method according to claim 19 wherein said anthracycline anti-cancer agent is doxorubicin.
		21. A method according to claim 19 wherein said anthracycline anti-cancer agent is epirubicin.
		22. A method according to either of claim 18 wherein said anthracycline anti-cancer agent is administered as an aerosolized liquid or powder.
		23. A method according to claim 22 wherein said anthracycline anti-cancer agent is doxorubicin or epirubicin and is administered as an aerosolized liquid.
		24. A method according to claim 22 wherein said anthracycline anti-cancer agent is doxorubicin or epirubicin and is administered as an aerosolized powder.

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TABLE I

Claims From USSN 10/066,831, 6,384,209  
 and US 6,419,901

CLAIMS FROM USSN 10/066,831 AFTER AMENDMENT	CLAIMS FROM US 6,384,209	CLAIMS FROM US 6,419,901
128. A method of treating cancer of the respiratory tract in a patient in need of treatment which comprises administering by inhalation a pharmaceutically safe and effective amount of an aerosolized vesicant anti-cancer agent, wherein said vesicant anti-cancer agent is unencapsulated and wherein and wherein the particle size of said aerosol is from about 0.1 $\mu\text{m}$ to about 10.0 $\mu\text{m}$ .	1. A method of treating cancer of the respiratory tract in a patient in need of treatment which comprises administering by inhalation a pharmaceutically safe and effective amount of a vesicant vinca alkaloid anti-cancer agent, wherein said anti-cancer agent is unencapsulated.	1. A method of treating cancer of the respiratory tract in a patient in need of treatment which comprises administering by inhalation a pharmaceutically safe and effective amount of a vesicant anthracycline anti-cancer agent, wherein said anti-cancer agent is unencapsulated.
129. A method according to Claim 128 wherein said anti-cancer agent is selected from the group consisting of anthracyclines, alkylating agents, vinca alkaloids, and taxanes.	2. A method according to claim 1 wherein said vinca alkaloid anti-cancer agent is selected from the group consisting of vincristine, vindesine, vinorelbine, and vindesine.	2. A method according to claim 1 wherein said anthracycline anti-cancer agent is selected from the group consisting of doxorubicin, epirubicin, daunorubicin, cytarabine, idoxorubicin and idarubicin.
131. A method according to Claim 129 wherein said alkylating agent is selected from the group consisting of mechlorethamine, mitomycin-C, dacarbazine, and mitomycin.	3. A method according to claim 2 wherein said vinca alkaloid anti-cancer agent is administered at a dosage of from about 0.1 $\text{mg}/\text{m}^2$ body surface area to about 80.0 $\text{mg}/\text{m}^2$ body surface area.	3. A method according to claim 2 wherein said anthracycline anti-cancer agent is selected from the group consisting of doxorubicin and epirubicin and idarubicin.
135. A method according to Claim 128 wherein said vesicant anti-cancer agent is administered by inhalation as an aerosolized liquid, powder or gas.	4. A method according to claim 2 wherein said vinca alkaloid is administered at a dosage of from about 12.0 $\text{mg}/\text{m}^2$ body surface area to about 30.0 $\text{mg}/\text{m}^2$ body surface area.	4. A method according to claim 1 wherein said anthracycline anti-cancer agent is doxorubicin.
136. A method according to Claim 135 wherein said aerosolized vesicant anti-cancer agent is administered as an aerosolized liquid.	5. A method according to claim 4 wherein said vinca alkaloid anti-cancer agent is administered at a dosage of from about 1.0 $\text{mg}/\text{m}^2$ body surface area to about 3.0 $\text{mg}/\text{m}^2$ body surface area.	5. A method according to claim 1 wherein said anthracycline anti-cancer agent is epirubicin.

Appl. 10066,831  
 Amtd. Dated 10/10/04  
 Reply to First Office Action of 04/27/2004

Table 1. Cont'

CLAIMS FROM USSN 10066,831	CLAIMS FROM US 6,394,209	CLAIMS FROM US 6,419,901
137. A method according to Claim 135 wherein said aerosolized anthracycline is administered as an aerosolized powder.	6. A method according to claim 5 wherein said vinca alkaloid anti-cancer agent is vincristine and wherein said agent is administered at a dosage of about 1.4 mg/m <sup>2</sup> body surface area.	6. A method according to claim 1 wherein said anthracycline anti-cancer agent is idarubicin.
146. A method according to Claim 128 wherein the particle size of said aerosol is from about 0.1 µm to about 10.0 µm.	7. A method according to claim 3 wherein said vinca alkaloid anti-cancer agent is vindesine and wherein said agent is administered at a dosage of about 6.0 mg/m <sup>2</sup> body surface area.	7. A method according to claim 1 wherein said anthracycline anti-cancer agent is administered by inhalation as an aerosolized liquid, powder or gas.
147. A method according to Claim 146 wherein the particle size of said aerosol is from about 1.0 µm to about 5.0 µm.	8. A method according to claim 7 wherein said vinca alkaloid anti-cancer agent is vinorelbine and wherein said agent is administered at a dosage of about 30.0 mg/m <sup>2</sup> body surface area.	8. A method according to claim 7 wherein said aerosolized anthracycline is administered as an aerosolized liquid.
148. A method according to Claim 147 wherein the particle size of said aerosol is from about 2.0 µm to about 2.5 µm.	9. A method according to claim 3 wherein said vinca alkaloid anti-cancer agent is vindesine wherein said agent is administered at a dosage of about 3.0 mg/m <sup>2</sup> body surface area.	9. A method according to claim 7 wherein said aerosolized anthracycline is administered as an aerosolized powder.
151. The method according to Claim 129 wherein said anti-cancer agent is an alkylating agent.	10. A method according to claim 1 wherein said vinca alkaloid anti-cancer agent is administered by inhalation as an aerosolized liquid, powder or gas.	10. A method according to claim 7 wherein said anthracycline is doxorubicin, epirubicin or idarubicin.
152. The method according to Claim 131 wherein said alkylating agent is methotrexamine	11. A method according to claim 10 wherein said aerosolized vinca alkaloid is administered as an aerosolized liquid.	11. A method according to claim 7 wherein said anthracycline anti-cancer agent is administered as an aerosolized liquid at a dosage of from about 3 mg/m <sup>2</sup> body surface area to about 130 mg/m <sup>2</sup> body surface area.
153. The method according to Claim 131 wherein said alkylating agent is mitomycin-C.	12. A method according to claim 10 wherein said aerosolized vinca alkaloid is administered as an aerosolized powder.	12. A method according to claim 7 wherein said anthracycline anti-cancer agent is administered as an aerosolized powder at a dosage of from about 3 mg/m <sup>2</sup> body surface area to about 130 mg/m <sup>2</sup> body surface area.

Appel 10/086,831  
 Amended, Dated 10/1/04  
 Reply to Final Office Action of 8/4/27/2004

Table 1, Cont'

CLAIMS FROM USSN 10/086,831	CLAIMS FROM US 6,394,209	CLAIMS FROM US 6,419,801
154. The method according to Claim 131 wherein said alkylating agent is dactinomycin.	13. A method according to claim 12 wherein said vinca alkaloid is vindesine or vincristine.	13. A method according to claim 1 wherein said anthracycline anti-cancer agent is administered at a dosage of from about 3 mg/m <sup>2</sup> body surface area to about 130 mg/m <sup>2</sup> body surface area.
155. The method according to Claim 131 wherein said alkylating agent is mitomycin.	14. A method according to claim 13 wherein said vinca alkaloid is vindesine or vincristine.	14. A method according to claim 1 wherein the particle size of said aerosol is from about 0.1 $\mu$ m to about 10.0 $\mu$ m.
	15. A method according to claim 1 wherein the particle size of said aerosol is from about 0.1 $\mu$ m to about 10.0 $\mu$ m.	15. A method according to claim 14 wherein the particle size of said aerosol is from about 1.0 $\mu$ m to about 5.0 $\mu$ m.
	16. A method according to claim 15 wherein the particle size of said aerosol is from about 1.0 $\mu$ m to about 5.0 $\mu$ m.	16. A method according to claim 15 wherein the particle size of said aerosol is from about 2.0 $\mu$ m to about 2.5 $\mu$ m.
	17. A method according to claim 16 wherein the particle size of said aerosol is from about 2.0 $\mu$ m to about 2.5 $\mu$ m.	17. A method according to claim 1 wherein one or more non-anthracycline vesicant anti-cancer agents are administered by inhalation at the same time as the anthracycline anticancer agent.
	18. A method according to claim 15 wherein said means for aerosolization is selected from the group consisting of metered dose inhalers, nebulizers, and dry powder inhalers.	18. A method of treating cancer of the respiratory tract in a patient which comprises administering to said patient a pharmacologically safe and effective amount of an aerosolized active drug substance which is an anthracycline anti-cancer agent, wherein said anthracycline anti-cancer agent is administered at a dosage of from about 3 mg/m <sup>2</sup> body surface to about 130 mg/m <sup>2</sup> body surface area, wherein said active drug substance is delivered to said patient using a means for aerosolization of said active drug substance, and wherein the particle size of said aerosolized drug substance is from about 0.1 $\mu$ m.
	19. A method according to claim 1 wherein one or more non-vinca alkaloid vesicant anti-cancer agents are administered by inhalation at the same time as the vinca alkaloid anticancer agent.	19. A method according to claim 18 wherein said anthracycline anti-cancer agent is selected from the group consisting of doxorubicin, epirubicin, and idarubicin.